

Applicant(s): P. Bonutti  
Application No.: 10/078,030  
Examiner: G. Jackson

### Remarks

Claims 1, 11, 65-79 are pending in this application and are presented for the Examiner's review and consideration. Claims 1, 66, and 69 have been amended and claim 64 has been cancelled. Applicant believes the claim amendments, cancellation, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### 35 U.S.C. § 112 Rejection

Claims 66 and 67 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subjected matter which Applicant regards as the invention. Specifically, the Examiner asserts that the penultimate line of claim 66 lacks antecedent basis for "the pointed end." Applicant traverses this rejection.

Referring to claim 1, from which claim 66 depends, the second to last line of the claim recites "wherein the end portion has a pointed end in the closed condition." As such, claim 1 provided the proper antecedent basis for "the pointed end" as recited in claim 66.

Accordingly, Applicant requests reconsideration and withdrawal of the § 112 rejection of claims 66 and 67.

#### 35 U.S.C. § 102 and § 103 Rejections Based On Ko

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,354,302 to Ko ("Ko"). For the reasons set forth below, Applicant respectfully submits that claim 1 is not taught or suggested by Ko.

Ko discloses a medical device for facilitating visual observation and manipulation of

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internal tissue. (Col 1, lns 8-12). FIG. 1 depicts a medical device 10, referred to as a dissectoscope, which includes an outer tubular sleeve 12, having an open end 14 for receiving an inner sheath member 16a, a blunt penetration end 18 (or tissue distending mechanism) and an adjustable prong device 20 for attaching the outer sleeve 12 to outer skin tissue located about an incision or opening in the patient as best seen in FIG. 8. (Col. 5, lns. 32-30). The penetration end 18 includes a plurality of wedge sections 22a-22d or leaflets which form a blunt conical end when the wedges are not expanded. (Col. 5, lns. 47-49). To use the dissectoscope 10, an incision is made into the skin sufficient to allow the outer sleeve 12 to be inserted through the opening caused by the incision. (Col. 8, lns. 37-40).

Ko does not disclose that the penetration end is a pointed end used to pierce an imperforate surface on the body tissue. In fact, Ko discloses that the penetration end is a blunt conical end in a non-expanded or closed condition, which in use, is inserted through an incision made into the skin.

In contrast, the present invention discloses that an insertion assembly 20 is used to position an anchor 22 relative to body tissue 24. (Page 4, lns. 25-26). The inserter assembly 20 includes a tubular outer member 30. (Page 5, lns. 5-6). A leading end portion 62 of the tubular member 30 is operable between a closed condition and an open condition. (Page 6, ln. 26 –page 7, ln. 1). When the tubular outer member 30 is in the closed condition as shown in FIG. 1, a point 66 is formed at the end of the tubular outer member 30. (Page 8, lns. 10-13). This point can initiate the formation of an opening in an imperforate surface 68 on the body tissue 24. (Page 8, lns. 13-15).

Independent claim 1 recites an apparatus for use in positioning an anchor member relative to body tissue. The apparatus includes a tubular member through which the anchor member is movable and has an end portion operable between a closed condition and an open condition. The end portion has a pointed end in the closed condition, which is configured and dimensioned for piercing an imperforate surface on the body tissue.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Ko. Additionally, claim 65 was rejected under 35 U.S.C. § 103(a) as being unpatentable

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over Ko. As claim 65 depends from claim 1, this necessarily includes all the elements of the base claim. Accordingly, Applicant respectfully submits that claim 65 is allowable over Ko at least for the same reasons.

#### 35 U.S.C. § 102 Rejection Based on Kensey

Claim 64, was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,021,059 to Kensey ("Kensey"). Claim 64 has been cancelled rendering the rejection of this claim moot.

Additionally, claims 68 and 72 were rejected under 35 U.S.C. §102(b) as being anticipated Kensey. As claims 68 and 72 depend from independent claim 1, which was not rejected based on Kensey, Applicant respectfully requests clarification of this rejection.

#### Allowable Subject Matter

Applicant acknowledges with appreciation the allowance of claims 11 and 73-79.

The Examiner objected to claims 69-71 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Claims 66 and 67 were indicated as being allowable if rewritten in independent form and to overcome the indefiniteness rejection. Applicant has rewritten claims 66 and 69 as required by the Examiner and has overcome the indefiniteness rejection. Accordingly, Applicant submits that these claims, as well as dependent claims 67, 70, and 71 are now in condition for allowance.

#### Conclusion

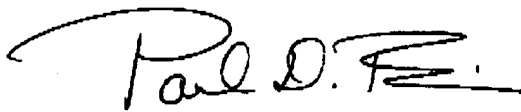
In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be

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appreciated since this should expedite the prosecution of the application for all concerned.

Please charge any required fee (or credit any overpayments of fees) to the Deposit  
Account of the undersigned, Account No. 500601 (Docket No. 782-A02-012-3).

Respectfully submitted,



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